



MAR 25 1999

Re: Tcslascan®  
Docket No. 98E-0479

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
U.S. Patent and Trademark Office  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,933,456 filed by Nycomed Salutar, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is Tcslascan® (magnafodipir trisodium), which was assigned new drug application (NDA) No. 20-652.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F.2d 392 (Fed. Cir. 1990).

The NDA was approved on November 26, 1997, which makes the submission of the patent term extension application on January 14, 1998, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: John Kappos  
Lyon & Lyon  
47th Floor  
633 West Fifth Street  
Los Angeles, CA 90071-2066

98E-0479

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

6177 '99 MAR 29 10:33  
Memorandum

Date: MAR 25 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application  
for **Teslascan**®

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number 98E-0479 stating that this particular patent is eligible for regulatory review.. The Patent Number is 4,933,456. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620, Thank you for your assistance,